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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,568	03/12/2002	Pamela Hirtzer	37200-0001	5616

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT PAPER NUMBER

1646

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/980,568	<b>Applicant(s)</b> HIRTZER ET AL.	
	<b>Examiner</b> Olga N. Chernyshev	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 98-122 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 98-122 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/27/02</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group V in Paper filed on December 02, 2003 is acknowledged. The traversal is on the ground(s) that "in view of the claim amendments there is unity of invention at least for Groups V and VI" and, further, that the special technical feature of the instant invention is also present in Groups III and IV (bottom at page 7 of the Response). This is not found persuasive because, as fully explained in section 2 of Paper No. 7, pursuant to 37 C.F.R. § 1.475 (d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto and, therefore, any feature which is the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-97 have been cancelled and claims 98-122 have been added as requested in the amendment filed on December 02, 2003. Claims 98-122 are pending in the instant application. Claims 98-122 correspond to original claims 90-92 of elected Group V.

Claims 98-122 are under examination in the instant office action.

### ***Sequence compliance***

2. This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 C.F.R. § 1.821 (a)(1) and (a)(2). However, this

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application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825.

Specifically, no sequence listing has been provided which includes the amino acid sequence presented on page 9 of the instant specification. Applicant needs to provide a computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO: ) be made in the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (703)308-1123. See M.P.E.P. 2422.04.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 98-122 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for prophylactically or therapeutically treating Alzheimer's disease in a human by administration of A $\beta$  peptide, does not reasonably provide enablement for a method for prophylactically or therapeutically treating Alzheimer's disease in a

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mammal by administration of A $\beta$  peptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 98-122 are drawn to a method for prophylactically or therapeutically treating Alzheimer's disease in a mammal by administration of A $\beta$  peptide in a sterile aqueous suspension. However, the instant specification fails to provide enough guidance for one skilled in the art on how to practice the instant method, thereby requiring undue experimentation to discover how to use Applicant's invention, as currently claimed.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

According to the knowledge in the art, Alzheimer's disease, which is the most common cause of dementia in the elderly, is disclosed to be affecting only human population (see Wen, 1998, J. Food and Drug Analysis, 6 (2), pp.465-476, for example). In view of the absence of information presented in the art or disclosed in the instant specification regarding any mammal other than human suffering from Alzheimer's disease, and also the total absence of the working examples, the instant specification is not found to be enabling for a method for treating Alzheimer's disease in a mammal. It would require undue experimentation and making a

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substantial inventive contribution for the skilled artisan to discover how to practice Applicant's invention commensurate in scope with the instant claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 98-122 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 98 is vague and indefinite for recitation "a sufficient amount" without stating what the amount is sufficient for. Clarification is required.
6. Claim 98 is also indefinite for recitation "an immunogenic response comprising antibodies to the A $\beta$  peptide". The metes and bounds of the recitation cannot be determined from the claim or the instant specification. An immunogenic response is a complex reaction, which includes process of antibody production rather than antibodies themselves.
7. Claim 98 is further vague and ambiguous for using terms "solution" and "suspension" interchangeably. For example, according to claim 98, "pH of aqueous solution" was adjusted to the level "sufficient to solubilize said A $\beta$  peptide" and the "resulting suspension" was filtered through a filter. A skilled artisan readily recognizes that terms "solution" and "suspension" have radically different meaning in the art. Therefore, the process of preparation of A $\beta$  solution/suspension, as presented in the claim, is vague and indefinite.

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8. Claim 98 is indefinite because recitation “and thereby prophylactically or therapeutically treat Alzheimer’s disease in the mammal” appears to be redundant or not in agreement with the content of the sentence. Clarification is required.

9. Claim 99 is vague and ambiguous for reciting “by use of about an effective amount”. The metes and bounds of the recitation cannot be determined from the claim.

10. Claim 99 is further indefinite for recitation “effective amount” without stating the objective of what the amount is effective for.

11. Claims 108 and 117 are vague and ambiguous because the metes and bounds of “pharmaceutically effective buffer” cannot be determined from the claims or the instant specification.

12. Claim 110 is vague and indefinite because it appears to recite two different suspensions, A $\beta$  and sucrose. Clarification is required.

13. Claim 116 is vague and ambiguous for not providing units for A $\beta$  concentration and, further for reciting “an effective amount” without providing an objective for effectiveness.

14. Claim 118 is indefinite for reciting “an effective amount” without stating what the amount is effective for.

15. Claim 120 recites the limitation "sterile composition" in claim 98. There is insufficient antecedent basis for this limitation in the claim.

16. Claims 121-122 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Claims 121-122 are directed to a method of treatment of Alzheimer’s disease by administration of a sterile aqueous suspension of A $\beta$ , “wherein the sterile aqueous suspension is administered parentally”, emphasis

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added. The instant specification, as filed, fail(s) to correspond in scope with what applicant(s) regard as the invention because there is no support of parental (to parents) administration of A $\beta$ , which indicates that the invention is different from what is defined in the claim(s).

17. Claims 100-107, 109, 111-115 and 119 are indefinite for being dependent from indefinite claims.

*Art of record*

18. Schenk, 1999 (WO 99/27944, 10 June 1999).

*Conclusion*

19. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices

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published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.



**OLGA N. CHERNYSHEV, PH.D.**  
**PATENT EXAMINER**

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